

May 26, 1999

1632 '99 JUN -9 A11:04

Dockets Management Branch (HFA-305)
Docket No. 98-N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: FDA's attempt to limit specialized pharmacies' ability to ship individually compounded prescription medications for personal use across state lines.

I am greatly dismayed to learn that large drug companies are trying to restrict, using the Food and Drug Administration as their vehicle, operations of small specialized pharmacies. I have been receiving compounded hormone preparations from the Women's Health Access in Madison, Wisconsin, for many years to treat difficult symptoms of Premenstrual Syndrome and Menopause.

Conventional, "one size fits all" drugs administered to women in this country "en masse" are not an option for me. I am extremely sensitive to most synthetic hormone preparations, e.g., Premarin, Provera, Climera patch, et al. Provera is especially difficult for many women, causing many PMS-like symptoms. Some of us cannot tolerate it at all. Beta-17 estradiol, the same molecule women make in their own bodies, as well as natural progesterone (not progestin or other derivatives) are only available at specialized pharmacies that compound individualized preparations according to a doctor's prescription.

There is nothing illegal going on here. These small pharmacies provide a service and product for a growing number of women in need of personalized treatment, using the utmost professionalism.

I can only assume that if the Food and Drug Administration goes ahead with these restrictions, its mandate to look after the interests of the consumer will have been violated. Limitations restricting the ability of women all over the country to obtain necessary and preferred hormone medications will invoke a lot of rage and contempt toward the FDA. We ask that you do not play the handmaiden to huge corporations trying to eliminate small pharmacies addressing the needs of a growing market.

Sincerely,

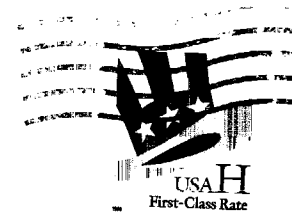
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